



# NSK-A-CE and NSK-B-CE

IVD  
ISO13485:2016



## Amino Acid Reference Standards and Free Carnitine/Acylcarnitine Reference Standards For MS/MS Newborn Screening

To aid the screening, diagnosis, and monitoring of neonates for inherited metabolic disorders (e.g., phenylketonuria, maple syrup urine disease, medium-chain and very long-chain acyl-CoA dehydrogenase deficiency), **Cambridge Isotope Laboratories, Inc. (CIL) is pleased to offer two sets of CE-marked standards – amino acid reference standards (NSK-A-CE) and carnitine/acylcarnitine reference standards (NSK-B-CE).** When used as directed (see instructions of use below), these products provide solutions of stable isotope-labeled standards at defined concentrations. Note: the metrics surrounding the concentrations have been rigorously validated for quality system compliance as a CE-marked, *in vitro* diagnostic (IVD) medical device for newborn screening. The ready-to-use assays can be used to measure and evaluate the concentrations of targets (amino acids in NSK-A-CE; free carnitine/acylcarnitines in NSK-B-CE) in a range of biosamples (e.g., dried blood spot, plasma, urine) by a variety of analytical techniques (e.g., FIA-MS/MS, LC-MS/MS, LC-MRM/MS).

### NSK-A-CE Device Description and Intended Use

Each vial of the NSK-A-CE reference standard (packaged 10 vials per box) contains a dry mixture of 12 stable isotope-labeled amino acids. Accurate and complete reconstitution of one vial's contents in 1 mL of high-purity solvent will produce the concentrations listed in the table below.

### Composition

Reference Standard	Mark	Conc. (µM)
L-Alanine (2,3,3,3-D <sub>4</sub> , 98%)	CE	500
L-Arginine-HCl (5- <sup>13</sup> C, 99%; 4,4,5,5-D <sub>4</sub> , 95%)	CE	500
L-Aspartic acid (2,3,3-D <sub>3</sub> , 98%)	CE	500
L-Citrulline (5,5-D <sub>2</sub> , 98%)	CE	500
DL-Glutamic acid (2,4,4-D <sub>3</sub> , 98%)	CE	500
Glycine (2- <sup>13</sup> C, 99%; <sup>15</sup> N, 98%)	CE	2500
L-Leucine (5,5,5-D <sub>3</sub> , 99%)	CE	500
L-Methionine (methyl-D <sub>3</sub> , 98%)	CE	500
L-Ornithine-HCl (5,5-D <sub>2</sub> , 98%)	CE	500
L-Phenylalanine (ring- <sup>13</sup> C <sub>6</sub> , 99%)	CE 0050	500
L-Tyrosine (ring- <sup>13</sup> C <sub>6</sub> , 99%)	CE 0050	500
L-Valine (D <sub>8</sub> , 98%)	CE	500

For sale in European Economic Area (EEA) – EU and EFTA – only.

### Method of Reconstitution

- Solubilize the dried-down mix in 1 mL of purified water:methanol (1:1).
- Vortex manually for 1 minute then auto-vortex for 30 minutes or until complete reconstitution is achieved.

Aliquots of this concentrated stock can then be processed, diluted, or stored (see usage specifications for guidelines).

### Usage Specifications

Criteria	Recommendation
Use	960 samples/vial
<b>Before reconstitution:</b>	
Storage	≤25°C, protect from light
Recommended shelf life	4 years
<b>After reconstitution:</b>	
Storage	Store refrigerated (2-8°C) in a tightly sealed vial. To maintain the integrity of the solution, store the sealed vials in a second sealed container.
Recommended shelf life	1 month

Warning: Irritant

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## NSK-B-CE Device Description and Intended Use

Each vial of the NSK-B-CE reference standard (packaged 10 vials per box) contains a dry mixture of stable isotope-labeled carnitine/acylcarnitines. Accurate and complete reconstitution of one vial's contents in 1 mL of high-purity solvent will produce the concentrations listed in the table below.

### Composition

Reference Standard	Abbrev.	Conc. (µM)
L-Carnitine (trimethyl-D <sub>9</sub> , 98%)	C0	152.0
O-Acetyl-L-carnitine-HCl (N-methyl-D <sub>3</sub> , 98%)	C2	38.0
O-Propionyl-L-carnitine-HCl (N-methyl-D <sub>3</sub> , 98%)	C3	7.6
O-Butyryl-L-carnitine-HCl (N-methyl-D <sub>3</sub> , 98%)	C4	7.6
O-Isovaleryl-L-carnitine-HCl (N,N,N-trimethyl-D <sub>9</sub> , 98%)	C5	7.6
O-Octanoyl-L-carnitine-HCl (N-methyl-D <sub>3</sub> , 98%)	C8	7.6
O-Myristoyl-L-carnitine-HCl (N,N,N-trimethyl-D <sub>9</sub> , 98%)	C14	7.6
O-Palmitoyl-L-carnitine-HCl (N-methyl-D <sub>3</sub> , 98%)	C16	15.2

### Method of Reconstitution

- Solubilize the dried-down mix in 1 mL of highly pure methanol.
- Vortex manually for 1 minute then auto-vortex for 30 minutes or until complete reconstitution is achieved

Aliquots of the concentrated stock can then be processed, diluted, or stored (see usage specifications for guidelines).

### Usage Specifications

Criteria	Recommendation
Use	960 samples/vial
<b>Before reconstitution:</b>	
Storage	≤8°C, protect from light
Recommended shelf life	1 year
<b>After reconstitution:</b>	
Storage	Store refrigerated (2-8°C) in a tightly sealed vial. To maintain the integrity of the solution, store the sealed vials in a second sealed container.
Recommended shelf life	1 month

Warning: Irritant    25°C  


Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. Avoid breathing dust/fumes/gas/mist/vapors/spray. Wash skin thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves, protective clothing/eye protection/face protection. IF ON SKIN: Wash with soap and water. IF INHALED: Remove the victim to fresh air. Keep at rest in a comfortable position. Call a POISON CENTER or doctor/physician if you feel unwell. IF IN EYES: Rinse with water for several minutes. Remove contact lenses.


### For sale in European Economic Area (EEA) – EU and EFTA – only.

*For professional use only.*

*In the US, CIL products are labeled "For Research Use Only. Not for use in diagnostic procedures."*

*Please visit [isotope.com](http://isotope.com) or see our "MS/MS Standards" catalog for additional information.*

 Keep away from sunlight

 Upper temperature limit

 Do not use if package is damaged

 *in vitro* diagnostic medical device



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